

FDLI'S FOOD *and* DRUG POLICY FORUM

What is the Best Way for Manufacturers and
Physicians to Apply Sunscreen to Avoid Being
Burned by the Final Sunshine Act Regulations?

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“What is the Best Way for Manufacturers and Physicians to Apply Sunscreen to Avoid Being Burned by the Final Sunshine Act Regulations?”

I. INTRODUCTION

Collaboration among physicians, teaching hospitals and the life sciences industry contribute to the design and delivery of life-saving drugs and devices, including treatments that have led to declining death rates over the last few decades for heart disease, stroke, cancer, and HIV/AIDS.¹

Approximately 83% of physicians have some type of relationship with industry.² Such relationships include conducting clinical trials and training physicians on how to safely use a new device.

While the overwhelming majority of these relationships are beneficial to the continued innovation and improvement of our health care system, “some payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.”³ However, even the Centers for Medicare & Medicaid Services (CMS) recognized that it has “no empirical basis for estimating the frequency of such problems, the likelihood that transparent reporting will reduce them, or the likely resulting effects on reducing the costs of medical care.”⁴

Nevertheless, several high profile cases and investigations involving unreported payments from manufacturers to physicians, and increased regulation of such relationships among industry, physician groups, institutions, and several states, provided the impetus for Congress to enact the Physician Payment Sunshine Act (“Sunshine Act”), a national transparency program for the public reporting of physicians’ financial relationships. While transparency will shed light on the nature and extent of these relationships, and may discourage inappropriate relationships, it is unclear whether Sunshine Act will lower health care costs or improve patient outcomes.

POLICY RECOMMENDATIONS

- Applicable Manufacturers Must Begin Training Employees on the Final Regulations and Put in Place New Policies and Procedures to Reduce Fraud and Litigation Risks and Identify High-Risk Relationships
- Applicable Manufacturers, Researchers and Teaching Hospitals Must Ensure Compliance with Reporting Research Payments to Avoid Violating FDA, NIH, and Institutional Requirements That May Call Into Question the Integrity of Research Data or Delay Research
- Officers Responsible for Attesting to Payment Reports and Employees Engaged in Sunshine Reporting Must Exercise Due Diligence to Avoid Potential Individual Liability

II. BACKGROUND

A physician survey conducted in 2003 and 2004 found that pharmaceutical companies paid more than a quarter of physicians in the preceding year for consulting, giving lectures, or enrolling patients in clinical trials.⁵ In 2005, these companies spent nearly \$7 billion on physician detailing and provided free samples with a retail value of more than \$18 billion.⁶ Researchers and faculty at academic medical centers (AMCs), as well as accredited continuing medical education (CME) providers also receive funding from industry.

Despite the enormous benefits of such collaboration, some have claimed that these relationships may also influence physicians' behavior in ways that undermine their independence and objectivity in prescribing, teaching, learning and practice. For example, some studies have shown that physician interactions with industry are associated with a greater willingness to prescribe newer, more expensive drugs.⁷ There has also been concern that clinical research funded by manufacturers is not transparent and may be more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies.⁸

In response to heightened legal and public scrutiny of physician–industry relationships, industry and physician groups, such as the American Medical Association (AMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), developed voluntary guidelines to manage interactions between manufacturers and physicians.⁹ In addition, a growing number of AMCs, professional medical associations, medical journals, and clinical guideline-writing committees have adopted stringent rules for interactions with the industry and several states¹⁰ have also enacted transparency laws. Notwithstanding these developments, some have expressed concern that industry guidelines are voluntary and States have been criticized for having payment data websites that are unsearchable or difficult to access. Given these concerns, coupled with the growing amount and scope of industry involvement in medical research, education, and clinical practice, the Medicare Payment Advisory Commission (MedPAC) and the Institute of Medicine (IOM)

recommended in 2009 that Congress enact a new regulatory program to address transparency in physician-industry relationships.¹¹ This led to Senators Charles Grassley and Herb Kohl to propose the Sunshine Act, which was eventually included in Section 6002 of the Patient Protection and Affordable Care Act (PPACA).

III. ISSUES IN DISPUTE

Proponents of transparency laws argue that comprehensive information about physicians' financial relationships with manufacturers would help payers and health plans examine whether and to what extent industry ties influence physicians' practice patterns, such as the drugs they prescribe and the procedures they perform. Such laws, proponents argue, would also enable patients to make better informed decisions when choosing physicians and making treatment decisions. Such laws might also deter physicians from participating in improper arrangements that violate industry and professional standards, which can sometimes lead to increased healthcare costs. Public reporting may also allow AMC's to verify the financial interests of their clinical investigators, and help media and researchers shed light on physician-industry interactions and identify potential conflicts of interest.

Despite these arguments, government officials have acknowledged that support "for greater transparency does not imply that all—or even most—of these financial ties are inappropriate or undermine physician-patient relationships."¹² In fact, much collaboration between researchers and the industry have benefited patients by translating research discoveries into new drugs and devices. In addition, manufacturers' marketing efforts may lead to increased use of beneficial drugs¹³ and keep physicians informed about new safety data, such as black box warnings. Furthermore, it is important to recognize that information may be of limited use to individual patients because they lack the medical expertise to understand the nature of particular relationships or arrangements.

Moreover, a public reporting system might discourage physicians and other providers from having legitimate research, consulting, education, and training arrangements with manufacturers that benefit patients and pose little risk of abuse. For example, a recent survey of over 1,000 physicians found that 66% would reduce their interactions with industry if false or incorrect information was disclosed.¹⁴ Finally, with an estimated cost of \$269 million in the first year and \$180 million annually, along with dedicating hundreds of thousands of hours and numerous employees, including training and education, the Sunshine Act will impose significant compliance costs on manufacturers and administrative costs on the government.

IV. RESEARCH AND RESPONSE

The Sunshine Act requires applicable manufacturers of drugs, devices, biological, or medical supplies covered under Medicare, Medicaid or CHIP, to report annually to CMS, in an electronic format, certain payments or other transfers of value ("payment") to covered recipients—physicians and teaching hospitals. The Act also requires AMs and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.¹⁵

AMs and GPOs must begin collecting the required data on August 1, 2013 and report payment data through December 31, 2013 to CMS by March 31, 2014. CMS then expects to publish the data for this period on a public website by September 31, 2014. AMs and GPOs that fail to comply with the reporting requirements may be subject to civil monetary penalties.

A. All Stakeholders Must Determine if They Are Applicable Manufacturers Required to Report

Applicable manufacturer (AM) is defined as an entity that “operates” in the U.S.¹⁶ and is “engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply ...” The definition does not include foreign entities that contribute to manufacturing, but have no presence in U.S.¹⁷ A covered product means that payment must be available under Medicare, Medicaid or CHIP and the product requires a prescription or premarket approval (devices). This includes products that are reimbursed separately or as part of a bundled payment.¹⁸

An entity that is under “common ownership”¹⁹ with an AM and “provides assistance or support”²⁰ to such entity also qualifies as an AM. The definition does not cover entities that only manufacture raw materials or components which are not covered products, *unless* under common ownership with an AM and assist or support manufacturing. The definition also specifically excludes distributors, wholesalers, repackagers, relabelers, and kit assemblers that do not hold title to any covered drug, device, biological or medical supply. It also excludes hospitals; hospital-based pharmacies and labs that manufacture a covered product solely for use by or within entity itself or by entity’s own patients; pharmacies; and compounding pharmacies that meet three specified requirements.

CMS finalized that AMs with less than 10% of total (gross) revenues of covered products must attest to that fact, and only have to report payments associated with those covered products. For AMs that have a separate operating division (e.g. animal health), the division need only report payments related to covered products if the division only produces non-covered products and does not meet the definition of providing assistance and support.²¹ Finally, entities that previously did not have any other covered product become an AM 180 days after its product becomes available for payment by CMS or CHIP.

B. Applicable Manufacturers Must Clearly Identify Which Transactions and Relationships Are With Covered Recipients and What Individuals are Excluded

Covered recipients (CRs) include physicians (MD’s, DO’s, dentists, dental surgeons, podiatrists, optometrists or chiropractors), and group practices. This includes all physicians that have a current license, regardless of whether they are enrolled with CMS or currently seeing patients. Medical residents are not CRs and payments to legal agents of AM that happen to have physicians on staff are not reportable payments. Teaching hospitals are also CRs and include any hospital receiving Medicare payments for direct graduate medical education (GME) or Indirect Medical Education (IME) payments.²² Payments to a veterinary school associated with hospitals are excluded. CMS will publish a list of hospitals once annually that will be available 90 days before the reporting year and

will include tax identification numbers. While Congress must amend the Sunshine Act to include any other CRs (e.g., nurses), States are able to require reporting for non-covered recipients without those provisions being preempted.

CMS also clarified that payments made “at the request of” or “designated on behalf of” a CR are different from indirect payments. If a CR directs that an AM provide payment to a specific entity or individual, rather than receiving it personally, then such payment is being made “at the request” of such CR, and therefore the AM must report the name of the CR, and the name of the entity paid or “individual” (name not required). If the CR neither accepts payment nor requests it be directed, then no reporting of the payment is required. When a CR does not receive payment, but an AM provides payment to another entity or individual in the name of the CR, then the payment has been “designated on behalf of” a CR, and therefore must be reported. For example, if a physician waives his payment but the AM donates the payment to charity on behalf of the physician, such payment must be reported. Accordingly, physicians must make clear prior to performing a specified service or entering into a contract whether their fee will be waived or paid to another individual or entity.

An important provision for AMs to analyze is whether certain physicians are “bona fide” employees of the AM, and thus exempt from the reporting requirements. CMS will use a case-specific analysis to determine if: (1) board members, (2) medical directors, (3) retirees, and (4) prospective employees are eligible for exclusion. Accordingly, when structuring employment arrangements with physicians, AMs should reference section 3121(d)(2) of the Internal Revenue Code, which CMS used to define “employee” in the final regulations. AMs should also consult guidance from HHS-OIG regarding the bona fide employment exception in the Anti-Kickback Statute (AKS). Finally, AMs should be prepared to report payments to prospective employee physicians (e.g., recruiting costs), including any travel, lodging, and meals.

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C. Applicable Manufacturers Must Use a Consistent and Transparent Methodology When Reporting Payment Information and Choosing the Nature of Payment

AMs must report a physician’s name and business address, NPI number (individual, not group),²³ specialty, state professional license number for at least one state, and the date²⁴ of payment. Payments made to physician group practices must be attributed only to physicians who requested the payment; on whose behalf the payment was made; or who are intended to benefit from the payment. For payment amount, AMs must make a reasonable, good faith effort to determine the “discernible economic value,” even if the payment has no discernible value to the CR or the CR does not request it. In addition, all aspects of the payment must be included when calculating, including tax and shipping. Next, AMs must report the form of payment, which can be: (1) cash or cash equivalent; (2) in-kind items or services; (3) stock, stock option, ownership interest; (4) dividend, profit or other return on investment.

Separate and apart from the form of payment, AMs must report one of sixteen nature of payment descriptions. While some are straightforward, such as travel; entertainment; gift; grant; honoraria; royalty or license; and space rental or facility fees (for teaching hospitals only), other categories require closer analysis. For example, CMS finalized that charitable contributions include, but are not

limited to, any payment made to an organization with tax-exempt status, which is not provided in exchange for any goods, items or services.²⁵ Thus, in circumstances where a physician provides consulting services to an AM, but requests that his payment for the services be made to a charity, it would be reported as a consulting fee with the physician as the CR, rather than a charitable contribution, because the physician directed the payment.

CMS also finalized that for meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), AMs must divide the total value of the food or beverage provided by the number of people who actually partook in the meal, including both CRs and non-covered recipients (such as support staff). If the per-person cost exceeds the minimum \$10 threshold, then the AM must report the food or beverage as a payment for each CR who actually partook in the group meal.²⁶ AMs must also report meals that are dropped off at a CRs office (e.g., sales rep) and other meals where the attendees are not controlled or selected by the AM. AMs must use the same attribution method for all meals regardless of whether the sales rep remained in the office for the entire meal. Even if the meal is under \$10, AMs must still track food and beverages provided to CRs in case their total annual payments exceed \$100.

If payment relates to marketing, education, or research of a covered product, the related covered product must also be identified. AMs may report up to five covered products related to each payment.²⁷ AMs must indicate “non-covered product” for payments related to a specific non-covered product and “none” if the payment is not related to any product (covered or not).²⁸ AMs may also voluntarily provide up to 200 characters of contextual information about a specific transaction.

Finally, AMs may, but are not required to, file an assumptions document with their reports to explain any assumptions made when collecting and reporting data and choosing particular nature of payment categories. Such documents will not be made public or provided to CRs, and will likely be protected from Freedom of Information Act requests under Exemption 4, which protects trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

D. Applicable Manufacturers, Researchers and Institutions Must Understand What Payments Are Eligible for Delayed Publication

The Sunshine Act allows CMS to grant a delay in publication for payments related to: (1) research²⁹ on, or development of, a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or (2) clinical investigations regarding a new drug, device, biological, or medical supply. CMS finalized, however, that payments in connection with research related to new applications of existing products will not be subject to delayed publication unless the research activities that resulted in the payment were not within the scope of a “clinical investigation.”³⁰ Payments for pre-clinical research, which includes “laboratory and animal research that is carried out prior to beginning any studies in humans, including FDA’s defined phases of investigation,” are also eligible for delayed publication. CMS will not delay payments for “business development activities.”

For the research payment to qualify for delay, it must be subject to a written agreement³¹ or contract or a research protocol. AMs wishing to have their research payments delayed still report the payment, but indicate to CMS its eligibility for delay. CMS will not publish the payment, and such data will not be subject to disclosure under 5 U.S.C. § 552, or any similar Federal, State, or local law, until FDA approves, licenses, or clears the product under research or four years after the date of payment, whichever comes first. The AM must continue to indicate such payment is eligible for delay annually and notify CMS if the product has received FDA approval or clearance. Payments will be made public “even if a product never received FDA approval, licensure or clearance.”

AMs must report the: (a) name of the research study; (b) name(s) of any related covered products; and (c) identifying information about each physician investigator.³² AMs may also voluntarily submit contextual information about the research and the ClinicalTrials.gov identifier. AMs must also report the total amount of the research payment, including costs associated with patient care such as diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items. Finally, when reporting research payments, AMs should separately report travel, meals, speaking, or other segregable activities, unless such payments are included in the written agreement and paid for through the large research contract.

E. Applicable Manufacturers and Physicians Must Be Clearly Aware of Which Payments or Transfers of Value Are Excluded From Reporting or Tracking

CMS finalized fourteen categories of payments that are excluded from reporting. States, however, can require reporting of categories excluded by the Sunshine Act, except for the \$10 minimum. Several exclusions are somewhat straightforward: discounts or rebates; loans of covered devices or devices under development for up to 90 days; contractual warranties; charity care; product samples; personal transfers of value; a physician acting as a patient (e.g., research subject); and legal services provided by a physician. Other categories, however, such as indirect payments, require great attention to ensure that AMs do not knowingly fail to report otherwise reportable payments.

CMS finalized that buffet meals, snacks or coffee provided at conferences or other similar large-scale settings, where it would be difficult to establish the identities of the physicians who partook in the meal or snack, are exempt from reporting. This exclusion does not apply to meals provided to select individual attendees at a conference where the AM can establish the identity of the attendees. Next, CMS excluded payments provided as compensation for speaking at a continuing education (CE) program, including prescriber education required by REMS, if three conditions are met.

First, the event at which the CR is speaking must meet the accreditation or certification requirements of one of five entities.³³ Second, the AM must not pay the CR speaker directly. Finally, the AM must not select the CR speaker or provide the third party (e.g., CE vendor) with a distinct, identifiable set of individuals to be considered as speakers for the CE program. AMs, however, must report payments for speaking at an unaccredited and non-certified CE program and for speaking engagements not related to medical education—each with their own category.

AMs will not be responsible for reporting under the “education category” or any other nature of payment category payments made to CE vendors that are used to subsidize attendees’ tuition fees for CE events. However, payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required. AMs are not required to report the provision of written materials that have been approved by FDA under a REMS for distribution to physicians, such as Dear Healthcare Provider letters, and other REMS educational materials may be excluded if they fall are intended for patient use.

One category of excluded payments AMs must pay close attention to is payments less than \$10. For practical purposes, AMs will still have to track all payments to CRs regardless of amount because reporting is required when the total annual value of payments provided to a CR exceeds \$100.³⁴ Small incidental items under \$10 (such as pens and note pads) that are provided at large-scale conferences or events open to the public, where it would be difficult for an AM to identify physician CRs, are exempt from the reporting requirements, including the need to track them for aggregation purposes.

AMs must also clearly understand when to exclude payments related to educational materials that directly benefit patients or are intended for patient use, which include an anatomical or wall model given to a physician to help explain to patients how a procedure would work. AMs may include overhead expenses, such as printing and time, in the exclusion as long as they are directly related to the development of the materials. Medical textbooks, marketing and promotional materials, and journal reprints do not fall within the exclusion.

Finally, an AM will not need to report indirect payments if the AM is unaware³⁵ of the identity of the CR during the reporting year and the second quarter of the subsequent year following the indirect payment.³⁶ In addition, if an AM requires, instructs, directs, or otherwise causes a third party to provide a payment, in whole or in part, to a CR, such payment must be reported, regardless of whether the AM specifies the CR. For example, if an AM provided an unrestricted donation to a physician professional organization, and the organization uses the donation to make grants to physicians, those grants would not constitute “indirect payments” because the AM did not require, instruct, or direct the organization to use the donation for grants to physicians.

F. Applicable Manufacturers, Covered Recipients and CMS Must Work Together to Ensure That Disputes and Corrections Are Resolved

After CMS collects and aggregates all payment reports, the agency will notify AMs and CRs that the data is available for review.³⁷ The online notification will inform CRs of the date their 45-day review period begins. Physicians will then be able to sign into CMS’ website securely, review only their data, and initiate a dispute if necessary, which gives AMs and CRs an additional 15 days to resolve the dispute. CMS, however, will not be involved in resolving the dispute. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period will be captured in the initial publication of the current reporting year of data on the public website. If the dispute is not resolved in this period, CMS will publish the payment with the notation “disputed.” For any corrections or omissions, the AM must re-submit and re-attest to the new data. After this

period, CMS will publish the data on its website, OPENPAYMENTS. The website must be searchable, understandable, easily aggregated and downloadable, provide background on industry-physician relationships, and include any enforcement activities taken.

AMs may be penalized by CMS or OIG for failing to timely, accurately or completely report payments, which includes failing to report an entire transaction or certain fields related to a transaction (e.g., date). Failure to report payments may be penalized \$1,000 to \$10,000 per payment, up to \$150,000 annually. Knowing failures to report payments may be penalized \$10,000 to \$100,000, up to \$1,000,000 annually. In determining the amount of penalty CMS or OIG will look at: (1) the length of time the AM failed to report; (2) the value of the payment; (3) the level of culpability; (4) the nature and amount of information reported in error; and (5) the degree of diligence exercised in correcting information reported in error.

Errors corrected during the 45-day review and correction and dispute resolution period will not be subject to penalties as long as the original submission was made in good faith. Errors or omissions outside of this period, however, are subject to penalties. Accordingly, AMs must submit corrected information to CMS immediately upon confirmation of the error or omission. AMs must also maintain, for at least 5 years (up to 9 years for delayed research payments), all books, contracts, records, documents, other evidence sufficient to enable CMS or OIG to audit, evaluate and inspect compliance with reporting requirements.

V. IMPACT OF POLICY RECOMMENDATIONS

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Compliance with the reporting requirements does not exempt AMs or CRs from any potential liability under the AKS or the False Claims Act (FCA). However, CMS made “clear that the inclusion of a payment ... on the public database does not mean that any of the parties involved were engaged in any wrongdoing or illegal conduct.” Moreover, the statute does not limit or ban such payments in any ways. Nevertheless, the government will use sophisticated data analytics to detect and prosecute health care fraud through Sunshine reporting and increased data sharing across government agencies.

A. Applicable Manufacturers Must Begin Training Employees on the Final Regulations and Put in Place New Policies and Procedures to Reduce Fraud and Litigation Risks and Identify High-Risk Relationships

Payments to physicians for speaking, travel, meals, research, consulting, and other services may violate the AKS if any one purpose of the payment is to induce physicians to prescribe medication or refer patients for goods or services paid for by CMS. Under PPACA, violations of the AKS can serve as the basis for FCA violations for all claims submitted that resulted from illegal remuneration. Public disclosure of physician investment or ownership interests in a manufacturer will also raise issues under the Stark Law. Moreover, AMs will also need to ensure compliance with a growing number of international transparency laws and foreign industry guidelines.³⁸

To prevent or reduce the likelihood of violations under the AKS, FCA, or Stark, AMs should consider implementing annual spending limits for physicians and establish a formal process to ensure that all payments are fair market value. AMs should ensure that all relationships are “in response to a legitimate need” and use a written agreement for all relationships to document such need and to ensure there is a connection between the competence of the CR and the purpose of the relationship, as well as a reasonable number of individuals hired to achieve the intended purpose.³⁹ In addition, AMs should implement periodic (monthly or quarterly) transparency evaluations and audits to monitor payments at pre-established benchmarks to avoid potentially suspect payment amounts or trends at year-end and to focus on high-risk payment category areas (e.g., speaking).⁴⁰ Companies should also consider establishing a transparency or disclosure committee, led by the Chief Compliance Officer, which includes staff from various business components (e.g., sales, medical affairs, education). The committee, which should report directly to the AMs Board, should monitor company payment trends, compliance with data collection requirements and provide oversight for the conduct of employees who engage in transactions with physicians (e.g., sales reps).⁴¹

In addition, because CMS did not specifically define what constitutes a “large-scale setting,” AMs should establish written policies and procedures for employees to determine when tracking is not required for meals, beverages, and small items (e.g., over 50 people). AMs must also have clear policies for employees to determine exactly what items are educational materials and are exempt from reporting and tracking. AMs should establish policies for employees regarding samples given to physicians, even though they are excluded from reporting, to ensure compliance with the Prescription Drug Marketing Act, as well as Section 6004 of PPACA. AMs must also have policies in place for employees to determine the proper standard of “awareness” when distributing grants, donations or other payments to third parties to ensure that any transactions qualifying as indirect payments are reported. Similarly, AMs and third parties need written policies for employees to determine whether meals, travel or other items of value (e.g., educational items) not directly paid by a sponsor, must be reported as indirect payments. These policies, which could also be outlined in an AMs assumption document, will be critical to avoid knowing violations that AMs should have reported. Such policies must also identify which employees or departments will be responsible for reporting which relationships or payments.

Physicians must also be extremely careful about the related covered product that AMs must report along with a particular transaction. Government officials may use a physician’s reported specialty to determine if payments are being made to a physician for an off-label use (e.g., a psychiatrist receives a payment related to an anti-epileptic drug). Accordingly, both AMs and physicians must clearly identify which covered products a particular relationship will pertain to, and should avoid relationships or activities with particular specialties that may suggest that the physician assisted in some form of off-label promotion.

Teaching hospitals must also avoid violating the AKS by ensuring that Pharmacy and Therapeutics Committees operate with a “strict conflicts of interest policy to assure that payments from industry to individuals on the Committee or to the institution cannot in practice or perception influence purchasing decisions.”⁴² Payment disclosure will also draw attention to “decisions by senior officials, including executives, Deans and Department Chairs, [who] may influence utilization of products

and services” as well as individuals who have a license or equity interest in a product or device utilized by or the subject of research at the institution.⁴³

Moreover, federal and state prosecutors will use payment data to call into question the medical necessity of treatment provided and to analyze claims tied to physicians, “including the number of surgeries conducted, and prescriptions for off-label use of medications or high cost drugs,” which could lead to FCA investigations.⁴⁴ In addition, collection of NPI numbers will raise concerns for AMs because it will permit researchers to link information on providers’ financial relationships to Medicare claims data (e.g., Part D drugs) to evaluate the impact of these interactions on prescribing practices. However, such data may be irrelevant. For example, a recent study showed that the transparency laws in Maine and West Virginia had a negligible to small effect on prescribing and healthcare expenditures related to statins and SSRIs.⁴⁵

Additionally, a *qui tam* lawyer or investigator may expose AMs to price reporting risks if they discover suspicious payments that may be characterized as “disguised discounts” that the AM failed to include in its report. For example, CMS or OIG may view a payment for consulting fees above fair market value as a discount that must be taken into account for government price reporting obligation purposes. In addition, the Sunshine Act may result in actions against AMs and physicians under state consumer protection laws, as was the case in Oregon, where the Attorney General recently brought an action against a physician for failing to disclose financial conflicts of interest to patients. Oregon also brought an action against a company, under the same law, for failing to disclose conflicts of interest when disseminating promotional material.

Finally, determining whether an AM should submit an assumptions document is problematic because reporting based on assumptions “would be open to prosecution,” and other HHS divisions, the Department of Justice (DOJ), or OIG could request access to the documents as part of an audit or investigation into an AM. On the other hand, reasonable and well-thought-out assumptions could assist in showing that any omission or improperly reported data was not the result of deliberate ignorance or reckless disregard that could lead to increased penalties. Accordingly, AMs must carefully weigh these concerns, and should draft such documents with an eye towards how an OIG or DOJ investigator or attorney would interpret them.

B. Applicable Manufacturers and Researchers Must Ensure Compliance with Reporting Research Payments to Avoid Violating FDA, NIH, and Institutional Requirements That May Jeopardize or Delay Research

While CMS does not need to verify research agreements, AMs must closely analyze such agreements to ensure compliance with the AKS and NIH and FDA regulations. For example, NIH regulations require institutions—such as AMCs—applying for Public Health Service (PHS) grants to obtain financial disclosure statements from investigators who plan to participate in the research and must manage, reduce, or eliminate significant financial interests that could be affected by the research. The institution must also report the existence of conflicting financial interests to the government agency that awards the grant and assure the agency that the interest has been managed, reduced, or eliminated. Thus, institutions and researchers will need to closely track when payments to a

physician exceed \$5,000—the threshold for a significant financial interest. Additionally, institutions and researchers will need to resolve the differences between NIH and Sunshine regulations regarding the reporting of any reimbursed or sponsored travel related to investigators’ institutional responsibilities.⁴⁶ FDA also has disclosure requirements for investigators that AMs and researchers must ensure compliance with to avoid FDA rejecting data or research and a product application being denied or delayed.⁴⁷ Discrepancies between Sunshine Act, NIH and FDA disclosures could lead to NIH freezing grant money for a particular researcher or entire institution, or FDA delaying or rejecting a product application. Additionally, physicians must be aware that the new reporting requirements may jeopardize their membership on NIH study groups, FDA advisory committees,⁴⁸ professional medical associations (including senior positions, e.g. chairs), and guidelines committees.

AMs must also be careful when reporting the related covered product associated with a research payment, particularly if the research is for a new or unapproved indication. Although such payments are delayed publication, it is still possible for CMS to share this data with OIG or DOJ, who could begin or enhance investigations into off-label promotion and any related false claims associated with such payments. Additionally, such payments could call into question the sufficiency of research data or journal articles used to support the safety and efficacy of off-label uses, causing FDA to reject a new indication. Such payments could also raise concerns about the data and research submitted to CMS to obtain listings in the medical compendia to establish that off-label uses are medically accepted and thereby eligible for coverage by federal healthcare programs, as was recently alleged in the Amgen settlement.⁴⁹

C. Officers Responsible for Attesting to Payment Reports and Employees Engaged in Sunshine Reporting Must Exercise Due Diligence to Avoid Potential Individual Liability

Another area of concern, particularly for executives of AMs, is the attestation requirement. Payment reports must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the AM that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. Such officers must also re-attest to any reports that require subsequent corrections. This requirement could expose such officers to liability under the *Park* doctrine and aggressive prosecutors may use such certifications as a means to prove that an individual knew or should have known of fraudulent or illegal activity.

Even more problematic, OIG may also use such certifications as evidence for both mandatory and permissive exclusions against executives and employees responsible for reporting. For example, OIG may take a broad interpretation of a knowing failure to report or correct a payment as a program related crime that requires mandatory exclusion, given that CMS is implementing the Sunshine Act, coupled with the broad definition of “related to the delivery of a healthcare item or service” and the Act’s legislative history and purpose to protect the integrity of payments made by CMS. Thus, an officer attesting to or an employee contributing to such inaccurate reporting could have committed a program related crime, which could result in a mandatory exclusion under 42 U.S.C. § 1327a-7(a)(1).

Alternatively, OIG may consider a violation of the reporting requirements and subsequent certification of such inaccurate reporting as a criminal offense “relating to fraud ... or other financial misconduct,” which could result in a permissive exclusion under 1327a-7(b)(1)(B). AMs should also be aware that subsection (b)(9) already allows permissive exclusion for any entity that fails to disclose required information regarding ownership and (b)(11) for failure to supply payment information. Thus, OIG may propose regulations to expand these sections to cover failures to disclose or inaccurate payments under the Sunshine regulations.

OIG may also permissively exclude any individual “who has a direct or indirect ownership or control interest in a sanctioned entity⁵⁰ and who knows or should know of the action constituting the basis for the [sanction]; or who is an officer or managing employee of such an entity.”⁵¹ OIG’s 2010 guidance explains that OIG will exercise a presumption in favor of exclusion under section (b)(15) where there is evidence that an owner, officer, or managing employee⁵² knew or should have known of the conduct leading to the exclusion or conviction of the entity, unless “significant factors” weigh against exclusion. Therefore, OIG might exclude a certifying officer who submits inaccurate payment reports and who should have known that such reports had errors or omissions. AMs must also be aware of the possibility that FDA may use evidence of an incorrect or inaccurate reporting of a research payment or other service related to product development to permissively debar officers.

Accordingly, executives and employees responsible for payment reporting must exercise due diligence and establish explicit checks and balances at every level of data collection to reduce potential individual liability. Additionally, given the tremendous burden Sunshine Act compliance will have on compliance officers and staff, stakeholders may want to open a dialogue with OIG to issue guidance or a special fraud alert, which could clarify OIG’s position on exclusion related to Sunshine Act noncompliance.

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VI. CONCLUSION

Shedding light on the interactions between AMs and CRs has several laudable goals. However, these objectives must be carefully weighed against the tremendous value physician-industry collaboration provides to the U.S. healthcare system and patients. Physicians should familiarize themselves with the regulations to reflect on the propriety of their relationships with industry and to determine whether a company really needs their expertise, the payment amount is reasonable, and the company is not just paying them for their brand loyalty. Physicians must also evaluate the size and frequency at which such interactions occur because government officials will be looking at physicians engaged by AMs on a regular basis or for large sums of money. Physicians must also be aware of how large and frequent payments may appear to their patients, colleagues and institutions, and must be prepared to engage in a balanced conversation with patients that explains, rather than defends, their relationships with industry. Lastly, physicians must realize that the Internal Revenue Service may use published payments and relationships to evaluate any inconsistencies or misreporting of taxes, and divorce attorneys may also use such payments.

To reduce the likelihood of inhibiting scientific discovery and collaboration, AMs and CRs must proactively work together to structure their relationships to ensure compliance with the final

Sunshine Act regulations and to minimize the risks associated with public disclosure of such payments, including federal and state investigations and litigation, as well as private plaintiff and consumer liability actions. Finally, CMS must work closely with all affected stakeholders to ensure that the public is clearly aware that financial ties alone do not signify an inappropriate or illegal relationship and beneficial relationships are not harmed.

ENDNOTES

1. Thomas Sullivan, *The Value of Medicine*, Policy and Medicine (Oct. 11, 2010), available at <http://www.policymed.com/2010/10/the-value-of-medicine.html>.
2. Thomas Sullivan, *Archives of Internal Medicine Study: Industry Physician Relationships Including Research Decreased Since 2004*, Policy and Medicine (Nov. 16, 2010) available at <http://www.policymed.com/2010/11/archives-of-internal-medicine-study-industry-physician-relationships-including-research-decreased-since-2004.html>.
3. Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests. 78 Fed. Reg. 9458, 9518 (Feb. 8, 2013) [hereinafter Final Sunshine Rule].
4. *Id.* at 9519.
5. Campbell, E. G., R. L. Gruen, J. Mountford, et al. 2007. A national survey of physician–industry relationships. *New England Journal of Medicine* 356, no. 17 (April 26): 1742–1750.
6. Donohue, J. M., M. Cevasco, and M. B. Rosenthal. 2007. A decade of direct-to-consumer advertising of prescription drugs. *New England Journal of Medicine* 357 (August 16): 673–681.
7. See e.g., Chren, M. M., and C. S. Landefeld. 1994. Physicians' behavior and their interactions with drug companies: A controlled study of physicians who requested additions to a hospital formulary. *Journal of the American Medical Association* 271, no. 9 (March 2): 684–689; Watkins, C., L. Moore, I. Harvey, et al. 2003. Characteristics of general practitioners who frequently see drug industry representatives: National cross sectional study. *British Medical Journal* 326 (May 31): 1178–1179; and Wazana, A. 2000. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *Journal of the American Medical Association* 283, no. 3 (January 19): 373–380.
8. See e.g., Als-Nielsen, B., W. Chen, C. Gluud, et al. 2003. Association of funding and conclusions in randomized drug trials: A reflection of treatment effect or adverse events? *Journal of the American Medical Association* 290, no. 7 (August 20): 921–928; Jørgensen, A. W., J. Hilden, and P. C. Gøtzsche. 2006. Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: Systematic review. *British Medical Journal* 333, no. 7572 (October 14): 782.
9. See e.g., American Medical Association. 1998. *E-8.061. Gifts to physicians from industry*. Chicago, IL: AMA. June; Pharmaceutical Research and Manufacturers of America. 2008. *PhRMA code on interactions with healthcare professionals*. Washington, DC: PhRMA. <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.
10. These include Minnesota; Vermont; West Virginia; Massachusetts; and Washington, DC.

11. MedPAC, *Public Reporting of Physicians' Financial Relationships*, Report to Congress: Medicare Payment Policy (Mar. 2009); Institute of Medicine, *Conflict of Interest in Medical Research, Education and Practice* (Apr. 21, 2009).
12. Final Sunshine Rule at 9510.
13. Powell, M. E., Pharmaceutical Research and Manufacturers of America. 2007. Oral testimony before the Special Committee on Aging, U.S. Senate. 110th Cong., 1st sess. June 27.
14. Thomas Sullivan, *Physician Payment Sunshine Act: Recent Survey Shows Physicians Still Unaware and Hospitals Concerned about Impending Regulation* (Sept. 19, 2012) available at <http://www.policymed.com/2012/09/physician-payment-sunshine-act-recent-survey-shows-physicians-still-unaware-and-hospitals-concerned-about-impending-regulat.html>.
15. This essay does not focus on the reporting provisions for GPOs.
16. Operates in U.S. means having a physical location or otherwise conducting activities within the U.S. See Final Sunshine Rule at 9461.
17. AMs cannot avoid reporting by indirectly paying a foreign entity; such a payment would have to be reported as an indirect payment if the entity operating in the U.S. was aware of the identity of the foreign entity. *Id.*
18. Meaning IPPS, OPPI, and other prospective payment systems (including chronic kidney disease drugs and products reimbursed through the end stage renal disease bundled payment system). *Id.* at 9466.
19. Common ownership means an entity "where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities." *Id.* at 9519.
20. "Assistance and support" means "providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution" of a covered product. An entity under common ownership, which produces the active ingredient for a covered drug and provides it to the AM for inclusion in the final product, would be considered necessary to the manufacturing of that product, since the AM could not produce the drug without the active ingredient. Conversely, an entity under common ownership that only aids the AM with human resources administrative functions would not be deemed necessary or integral since such functions are not directly involved with any manufacturing processes. *Id.* at 9463-64.
21. This includes payments made directly by the operating division and payments made indirectly by AM through separate operating division (reported as indirect payment). *Id.* at 9464.
22. Payments to non-healthcare departments at universities affiliated with a teaching hospital, however, are not reportable, except if meant as a pass through. *Id.* at 9468.
23. Not reporting an NPI may amount to inaccurate reporting that may be subject to penalties. AM's must demonstrate a good faith effort to obtain an NPI either by requesting it from a physician, checking the NPPES or calling the NPPES help desk. AMs may leave NPI blank if a good faith effort is made, however, if CMS finds the NPI number, an AM may be required to resubmit and re-attest the updated data. *Id.* at 9468-69.

24. For payments made over multiple dates (rather than as a lump sum), AMs may choose whether to report each payment as *separate line item* using the dates the payments were each made, or as a *single line item* for the total payment using the first payment date as the reported date. Aggregated payments should not cross years; in other words, AM's should not move payments from one year to another. AM's must use a consistent method for reporting dates and indicate their chosen methodology in their assumptions document. For example, for all flights, AM's should report either the flight date or ticket purchase date. For small payments reported as a single line item, AMs must report the date that the first bundled small payment was provided to the CR. *Id.* at 9473-74, 9523.
25. Payments to tax-exempt teaching hospitals would be considered and reported as charitable contributions, unless the payments are for expected services or benefits, such as consulting services or rental of space in a hospital for an event. *Id.* at 9478.
26. For example, a sales representative brings a catered lunch costing \$165 to a 10-physician group practice. Six of the ten physicians and five support staff participate in the meal. Because the meal cost \$15 per participant (\$165/11 participants = \$15), the meal needs to be reported for the 6 physicians who participated in it. However, the meal does not need to be reported for the 4 other physicians in the group who did not partake in the meal. In addition, the names of the support staff would not need to be reported since they are not covered recipients. However, CMS recognized that "in other contexts, transfers of value to a physician's office support staff (which may include meals) may constitute transfers of value to the physician." *Id.* at 9478-79.
27. AMs must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the AM must indicate the name registered on clinicaltrials.gov. For devices and medical supplies, AMs must report either the name under which the device or medical supply is or was marketed; or the therapeutic area or product category. *Id.* at 9475.
28. If the payment is related to at least one covered product and at least one non-covered product, AMs must report the name(s) of the covered products and may indicate "non-covered products" in addition. *Id.* at 9474.
29. CMS defined research by adopting the same definition used in the PHS Act, section 50.603. Research includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations for drugs, biologicals, and approval trials for devices (including medical supplies). CMS also clarified that new generic products will be considered new products, including drugs receiving approval under an ANDA, and devices under the 510(k) process. *Id.* at 9482.
30. Material transfers (e.g., provision of a protein) to a researcher for discovery collaboration do not need to be reported when not part of a commercial or marketing plan and precede the development of a new product because such transferred material does not have an independent value at such an early stage of the research process. *Id.* at 9483.
31. This includes an unbroken chain of agreements that link an AM with a CR constitutes a research agreement. For example, an agreement between an AM and a contract research organizations (CRO), between a CRO and a site management organization (SMO), and then between an SMO and a teaching hospital would be considered a continuous chain of agreements constituting a research agreement. *Id.* at 9482.

32. Including name, NPI, State professional license number(s) for at least one state, specialty and primary business address. The study name and covered product are not required for pre-clinical research. *Id.* at 9483-84.
33. Specifically, the event must meet the standards of one of the following: Accreditation Council for Continuing Medical Education, American Academy of Family Physicians, American Dental Association's Continuing Education Recognition Program, American Medical Association, and American Osteopathic Association. §403.904(g)(1)(i).
34. CMS did provide some flexibility in reporting small payments so that AMs may either report them individually or bundled with other small payments in the same nature of payment category, as long as AM is reporting consistently and clearly indicating the method they are using in their assumption document. Final Sunshine Rule at 9485.
35. An AM is unaware of the identity of a covered recipient if the AM does not know the identity of the CR. *Id.* at 9525. The definition of "know" provides that a person has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information. *Id.* at 9489.
36. For example, if an AM hires a market research firm for a double-blinded market research study and pays physicians \$50 to respond. This would not be an indirect payment because the third party's involvement is specifically to maintain the anonymity of the respondents and the sponsor. *Id.* at 9490.
37. Either through list serves, online postings or direct email for those that pre-register. *Id.* at 9499.
38. This includes France, the Netherlands, Slovakia, Australia, China, Croatia, Denmark, Japan, the Association of the British Pharmaceutical Industry, the International Federation of Pharmaceutical Manufacturers & Associations, and the European Federation of Pharmaceutical Industries & Associations.
39. Sunshine Final Rule at 9480 (referring to consulting fees).
40. Meenakshi Datta, *Beyond Sunshine: Looking Ahead to Fraud and Abuse Risks Raised by Transparency Reports, Presentation at Disclosure Summit (Feb. 20, 2013).*
41. *Id.*
42. Tracy E. Miller, *The Payment Sunshine Act: Assessing the Compliance Risks for Healthcare Providers*, AHLA Connections (Aug. 2011) at 26.
43. *Id.*
44. *Id.*
45. Pham-Kanter, G., et al. *Effect of Physician Payment Disclosure Laws on Prescribing.* *Arch Intern Med.* 2012; 172(10):819-821 (May 28, 2012).

46. Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, Final Rule, 76 Fed. Reg. 53256, 53289 (Aug. 25, 2011).
47. 21 CFR § 54.4. *See also* FDA Draft Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators (May 2011).
48. *See* FDASIA § 1142.
49. U.S. Dep't. of Justice, "Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY; Pays \$762 Million to Resolve Criminal Liability and False Claims Act Allegations" (Dec. 19, 2012), *available at* <http://www.justice.gov/opa/pr/2012/December/12-civ-1523.html>.
50. A "sanctioned entity" is defined as an entity that has been: (a) convicted of any offense under 1320a-7(a) (*i.e.*, offenses that require mandatory exclusion); (b) convicted of an offense described in 1320a-7(b)(1), (2), or (3) (*i.e.*, the first three offenses that can lead to permissive exclusion listed above); or (c) excluded from participation under a Medicare program or a state healthcare program. 42 U.S.C. § 1320a-7(b)(15) (B).
51. 42 U.S.C. § 1320a-7(b)(15).
52. OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, (Oct. 20, 2010) at 2. The guidance also applies to officers, general or business managers, directors, or administrators who have managerial or operational control or who have a direct or indirect role in the day-to-day operations of the entity. *See also* 42 C.F.R. § 1001.1051.

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